

## SUMMARY OF RESPONSE

### *Detailed Action*

#### ***Claim Rejections -35 USC § 112***

1. The Examiner states: "Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The written description fails to clearly teach the newly recited step of 'stimulating collagenesis without coagulation of collagen.'"

#### ***Claim Rejections - 35 USC § 103***

2. The Examiner states: "Claims 1-3, 6, and 8-11 are again rejected under 35 U.S.C. 103(a) as being unpatentable over O'Donnell, Jr. U.S. Patent 6,106,514 in view of Purchio et al. U.S. Patent 5,599,788.

O'Donnell, Jr. discloses apparatus and method for treating subsurface layer of skin, the method comprising the steps of:

applying anti-inflammatory, anti-oxidant (wound healing) pharmaceutical agent to the skin (Col. 3, lines 21-26); and irradiating the skin with laser energy sufficient to cause stimulation of collagen remodeling for the purpose of effecting the tightening of the skin and reducing wrinkles without significantly altering the epidermis (see claims 1-3).

As to claim 3, O'Donnell, Jr. applies mechanical energy to the skin tissue (Col. 6, lines 6-10).

As to claim 8, his treatment reduces wrinkles. Therefore, since wrinkles result from photo-damaged and/or aging skin, he provides the claimed method step.

Although O'Donnell, Jr., described above, discloses pharmaceutical agent to enhance the treatment, he does not teach the use of growth factor such as H3 protein to promote the healing

process.

However, Purchio et al. disclose a method of producing recombinant transforming growth factor - induced H3 protein and its use to accelerate wound healing (see col. 4, line 65 to col. 5, line 9).

They further teach that H3 protein may be combined with conventional chemotherapy and radiation treatment to increase the over all treatment efficiency (col. 4, lines 58—60).

Therefore, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify O'Donnell, Jr. and apply a growth factor such as H3 protein to the skin as taught by Purchio et al. in order to accelerate the wound healing and to enhance the over all treatment efficiency.

As to claim 6 of the instant application, claim 3 of O'Donnell, Jr. teaches the claimed limitation."

3. The Examiner states: "Claim 7 is again rejected under 35 U.S.C. 103(a) as being unpatentable over Tankovich et al. U.S. Patent 5,817,089 in view of Purchio et al. (788).

Tankovich et al. disclose phototherapy treatment methods for the reduction and removal of unwanted hair and the mitigation of skin conditions such as acne and seborrhea. However, they do not apply wound healing promoter composition to the skin to enhance the healing process.

Purchio et al., described above, teach the use of a wound healing protein, which may be combined with conventional chemotherapy and radiation treatment to increase the over all treatment efficiency. Therefore, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify the invention of Tankovich et al. with Purchio et al. to apply a wound healing protein to the skin being treated so as to enhance the wound healing process and improve the over all treatment efficiency."

4. The Examiner states: "Claims 1-3, 6 and 8-11 are again rejected under 35 U.S.C. 103(a) as being unpatentable over O'Donnell, Jr. U.S. Patent 6,106,514 in view of Hale et al. U.S. Patent

5,607691.

O'Donnell, Jr. discloses apparatus and method for treating subsurface layer of skin, the method comprising the steps of:

applying anti-inflammatory, anti-oxidant (wound healing) pharmaceutical agent to the skin (Col. 3, lines 21-26); and

irradiating the skin with laser energy sufficient to cause stimulation of collagen remodeling for the purpose of effecting the tightening of the skin and reducing wrinkles without significantly altering the epidermis (see claims 1-3).

As to claim 3, O'Donnell, Jr. applies mechanical energy to the skin tissue (Col. 6, lines 6-10).

As to claim 8, his treatment reduces wrinkles. Therefore, since wrinkles result from photo-damaged and/or aging skin, he provides the claimed method step.

Although O'Donnell, Jr., described above, discloses pharmaceutical agent to enhance the treatment, he does not teach the use of growth factor such as H3 protein to promote the healing process.

Hale et al. disclose a method for treating the skin of a patient, the method comprising the steps of: delivering to the skin a pharmaceutical agent such as H3 protein (Col. 26, lines 22-39; Col. 45, lines 35-41; and Col. 51, lines 17-40); and applying EM energy to the skin being treated (Col. 50, lines 27-39).

Therefore, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify O'Donnell, Jr. and apply a growth factor such as H3 protein to the skin as taught by Hale et al. in order to accelerate the wound healing and to enhance the over all treatment efficiency."

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***Response to Arguments***

5. The Examiner states: "Applicant's arguments filed on September 27, 2004, have been fully considered but they are not persuasive. The applicant's argument is mainly based on the newly recited term in the claims that the claimed invention is directed to treatment methods for 'stimulates collagenesis without coagulation of collagen.'" However, the applicant's written description fails to clearly teach this recitation. Furthermore, O'Dannell ('514) clearly teaches that his invention stimulates increase of new collagen (see the abstract).
- The applicant further argues that there is a difference between the treatment energy disclosed in the present application and the one used by O'Dannell ('514). However, the applicant's claims fail to recite the parameters of the treatment energy."

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## CLAIMS AMENDMENTS

- Claim 1 (currently amended) A method for treatment of skin comprising:  
treating a subsurface layer of skin with a source of energy sufficient to cause stimulation of collagen biosynthesis remodeling without ~~coagulation of collagen~~ thermal damage to the epidermis, in conjunction with applying a wound healing composition to the skin, thereby achieving improved collagenesis in the skin.
- Claim 2 (original) The method of Claim 1 wherein the energy is electromagnetic energy.
- Claim 3 (previously presented) The method of Claim 1 wherein the energy is mechanical energy.
- Claim 4-5 (canceled)
- Claim 6 (previously presented) The method of Claim 1 wherein the treatment is repeated serially with more than one day between any successive treatments.
- Claim 7 (currently amended) A method for treatment of acne scars in skin, comprising:  
treating subsurface and surface layers of the skin with a source of energy in order to stimulate ~~collagenesis~~ collagen biosynthesis in the skin without ~~coagulation of collagen~~ thermal damage to the epidermis, in conjunction with applying a wound healing promoter composition which enhances a healing response in the skin, thereby improving the appearance of the acne scars.

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Claim 8 (currently amended) A method for treatment of photodamaged skin, comprising:  
treating the skin with a source of energy which stimulates ~~cotlagenesis~~ biosynthesis of collagen  
without ~~coagulation of collagen~~ thermal damage to the epidermis, in conjunction with applying a wound  
healing promoter composition to the skin which enhances a healing response, thereby improving the  
appearance of the photodamaged skin.

Claim 9 (currently amended) A method for treatment of wrinkled skin, comprising:  
treating the skin with a source of energy which stimulates ~~cotlagenesis~~ biosynthesis of collagen  
without ~~coagulation of collagen~~ thermal damage to the epidermis, in conjunction with applying a wound  
healing promoter composition to the skin which enhances a healing response, thereby improving the  
appearance of the wrinkled skin.

Claim 10 (currently amended) A system for treatment of skin, comprising:  
a source of energy which is sufficient to stimulate ~~cotlagenesis~~ biosynthesis of collagen in the  
skin without ~~coagulation of collagen~~ thermal damage to the epidermis; and  
a wound healing promoter composition which enhances a healing response in the skin to  
accelerate cotlagenesis therein, thereby resulting in improved appearance of skin.

Claim 11 (currently amended) A method for treatment of tissue comprising the following  
steps:  
causing a subdermal stimulation of collagen biosynthesis without ~~coagulation of collagen~~ thermal  
damage to the epidermis using a source of electromagnetic energy; and  
applying a wound healing promoter composition to the tissue, such that collagenesis, repair and  
healing improvement of tissue is accelerated.